K112055 STERIS®

DEC 16 2011

510(k) Summary
For
AMSCO Chimeron Medium Steam Sterilizer

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 639-4459

Contact: Robert F. Sullivan
Senior Director
FDA Regulatory Affairs
Telephone:(440) 392-7695
Fax No: (440) 357-9198

Summary Date: July 15th, 2011

1. Device Name

Trade Name:	AMSCO Chimeron Medium Steam Sterilizer
Models:	36H, 48H, 60H, 36SL, 48SL, 60SL, 36CH, 48CH, 60CH, 36CSL, 48CSL and 60CSL
Common/Usual Name:	Steam Sterilizer
Classification Name:	Steam Sterilizer (21 CFR 880.6880) Product Code FLE

2. Predicate Device

K010865, AMSCO Century Medium Steam Sterilizer, product code [FLE] cleared May 31st, 2001.

3. Description of Device

The AMSCO Chimeron Medium Steam Sterilizers (Models 36H, 48H, 60H, 36SL, 48SL, 60SL, 36CH, 48CH, 60CH, 36CSL, 48CSL and 60CSL) are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in the following configuration:

- *Prevacuum* – equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.

The chamber sizes of the proposed AMSCO Chimeron Medium Steam Sterilizer Models are as follows:

- 26" x 37.5" x 36" (Models 36H, 36CH, 36SL, 36CSL)
- 26" x 37.5" x 48" (Models 48H, 48CH, 48SL, 48CSL)
- 26" x 37.5" x 60" (Models 60H, 48CH, 48SL, 48CSL)

4. Intended Use

The AMSCO Chimeron Medium Steam Sterilizers (Models 36H, 48H, 60H, 36SL, 48SL, 60SL, 36CH, 48CH, 60CH, 36CSL, 48CSL and 60CSL) are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in the following configuration:

- *Prevacuum* – equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.

The AMSCO Chimeron Medium *Prevacuum* Steam Sterilizers are equipped with the following factory-validated sterilization cycles (Table 5-1):

Table 5-1

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Factory Default	Recommended Load
Prevac	270°F (132°C)	4 minutes	20 minutes	Yes	Fabric Packs. *Refer to Table 5-2 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	30 minutes	Yes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 5-2 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	5 minutes	No	Single Fabric Pack
Prevac	275°F (135°C)	3 minutes	30 minutes	Yes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 5-2 for recommended quantities.*
Gravity	250°F (121°C)	30 minutes	15 minutes	No	Fabric Packs. *Refer to Table 5-2 for recommended quantities.*
Gravity	270°F (132°C)	15 minutes	30 minutes	No	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 5-2 for recommended quantities.*
Gravity	250°F (121°C)	30 minutes	30 minutes	No	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 5-2 for recommended quantities.*

Gravity	270°F (132°C)	25 minutes	15 minutes	No	Fabric Packs. *Refer to Table 5-2 for recommended quantities.*
Liquid*	250°F (121°C)	45 minutes	N/A	No	*Validated with 3 1000ml bottles. Refer to Table 5-3 for recommended full load quantities.*
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	Yes	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Yes	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	Yes	N/A

*The liquid cycle is for non-patient contact use only.

The following table lists STERIS' full loads by sterilizer size:

Table 5-2
AMSCO Chimeron Medium Steam
Sterilizer full load per sterilizer size

Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
26" x 37.5" x 36"	9	18
26" x 37.5" x 48"	12	30
26" x 37.5" x 60"	15	36

The following table is a guideline for liquid cycle processing. The liquid cycle is for non-patient contact use only.

Table 5-3
AMSCO Chimeron Medium Steam
Sterilizers Liquid Cycle Guideline

Sterilizer Size	Number of Containers for full load	Number of Containers for validation	Volume of Liquid In One Container	Minimum Recommended Sterilize Time at 250°F (121°C)
26" x 37.5" x 36"	112	3	1000 ml	45 minutes
26" x 37.5" x 48"	154	3	1000 ml	45 minutes
26" x 37.5" x 60"	196	3	1000 ml	45 minutes

5. Description of Safety and Substantial Equivalence

A summary of the technological characteristics of the device subject of this premarket notification in comparison to those of the predicate devices is included in Table 5-4.

Table 5-4
Summary of the Proposed and predicate Devices
Technological Characteristics

General Sterilizer Features	AMSCO Chimeron Medium Steam Sterilizer	AMSCO Century Medium Steam Sterilizer (K010865)
Intended Use	A steam sterilizer intended for sterilization of non-porous and porous, heat- and moisture-stable materials in healthcare facilities.	A steam sterilizer intended for sterilization of non-porous and porous, heat- and moisture-stable materials in healthcare facilities.
Operating Principle	Steam is the sterilizing agent.	Steam is the sterilizing agent.
Sterilization Cycles Offered	Prevac Gravity Liquid	Prevac Gravity Liquid SFPP
Chamber Sizes	26" x 37.5" x 36" 26" x 37.5" x 48" 26" x 37.5" x 60"	26" x 37.5" x 36" 26" x 37.5" x 48" 26" x 37.5" x 60"
Chamber Door	Type 316L stainless steel Hinge or Horizontal Sliding	Type 316L stainless steel Hinge or Horizontal Sliding
Shell Assembly	Type 316L stainless steel ASME certified	Type 316L stainless steel ASME certified
Control Technology	Embedded Controller Touch Screen 320 x 240 Pixel Display Ink on Paper Printer	Embedded Controller Touch Screen 320 x 240 Pixel Display Ink on Paper Printer
Process Monitors	Chamber Transducer Dual Element Chamber Drain Sensor	Chamber Transducer Dual Element Chamber Drain Sensor
Safety Devices	Pressure Relief Valve Chamber Float Switch Emergency Stop Switch on Powered, Sliding Door Units	Pressure Relief Valve Chamber Float Switch Emergency Stop Switch on Powered, Sliding Door Units

Effectiveness

Effectiveness of sterilizer function and exposure time recommendations was demonstrated by complete kill of biological indicators and by verifying an appropriate safety factor or sterility assurance level (SAL) of at least 10^{-6} probability of survival. STERIS validates its sterilization cycles using recommended practices, standards and guidelines developed by independent organizations such as the Association for the Advancement of Medical Instrumentation (AAMI). The AMSCO Chimeron Steam Sterilizers have been validated to meet the requirements of ANSI/AAMI ST8: 2008, December 2008.

The results of the AMSCO Chimeron Steam Sterilizer verification studies demonstrate that the sterilizers perform as intended. These reports can be found in Exhibits P and Q:

- Exhibit P: AAMI ST8: 2008 Validation Study for AMSCO Chimeron Medium Series 26" x 37.5" x 60"
- Exhibit Q: Software Verification and Validation Report; Technical Report No. 2011-022 for AMSCO Chimeron Sterilizer

The results are summarized as follows:

- Empty chamber testing was performed as described in Section 5.4.2.5 of ANSI/AAMI-ST8, for the Prevac, Gravity, and Liquid cycles. These cycles demonstrated that the sterilizer is capable of providing steady state thermal conditions within the chamber that are consistent with the predicted sterility assurance level (SAL) in the load. The sterilizer meets the requirements of Sections 4.4.2 of ANSI/AAMI-ST8.
- All GRAVITY cycles were validated using the fabric test pack, described in Section 5.5.2.1 of ANSI/AAMI-ST8, and were qualified according to Section 5.5.2 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, moisture retention of less than 3% increase in presterilization test pack weight, and no evidence of wet spots.
- All GRAVITY cycles were validated using full load instrument trays, described in 5.5.4.1 of ANSI/AAMI-ST8, and were qualified according to Section 5.5.4 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} using half-cycle cycle analysis, moisture retention of less than 20% increase in presterilization weight of the towel, and no evidence of wet spots on the outer wrapper.
- All PREVAC cycles were validated using the fabric test pack, described in Section 5.5.2.1 of ANSI/AAMI-ST8, and were qualified according to Section 5.5.2 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, moisture retention of less than 3% increase in presterilization test pack weight, and exhibited no wet spots.

- All PREVAC cycles were validated using full load instrument trays, described in 5.5.4.1 of ANSI/AAMI-ST8, and were qualified according to Section 5.5.4 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} using half-cycle analysis, moisture retention of less than 20% increase in presterilization weight of the towel, and no evidence of wet spots on the outer wrapper.
- All LIQUID cycles were validated using three 1,000 ml flasks, described in Section 5.5.3.1 of the ANSI/AAMI-ST8, and were qualified according to Section 5.5.3 of ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, water loss not exceeding 50 ml, and automatic sealing of the flask closure. The liquid cycle is for non-patient contact use only.
- The DART cycle was validated using the Bowie-Dick Test Pack, as described in 5.6.1.1 of the ANSI/AAMI-ST8, was qualified according to Section 5.6.1 of the ANSI/AAMI-ST8, and demonstrated a uniform color change throughout the test sheet. The DART cycle uses the same dynamic air removal routines as the 270°F Prevac cycle.
- The software validation for the cycle operation was performed according to FDA's moderate level of concern recommendations provided in the document *"Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices (05/11/05)."*

Safety

STERIS sterilizers including the AMSCO Chimeron Steam Sterilizers have been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards. The AMSCO Chimeron Steam Sterilizers comply with the following requirements:

- ANSI/UL 61010-1 2nd Edition (7/22/2005) "Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 1 General Requirements.
- CAN/CSA C22.2 No. 61010-1 2nd Edition (7/12/2004) "Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 1 General Requirements".
- UL 61010A-2-041 1st Edition (3/27/2002) "Particular Requirements for Autoclaves Using Steam for Treatment of Medical Materials and for Laboratory Processes"
- CAN/CSA C22.2 No 1010.2.041 (R2004) "Particular Requirements for Autoclaves Using Steam for Treatment of Medical Materials and for Laboratory Processes".
- ASME Boiler Pressure Vessel Code, Section VIII (Division 1) (7/1/2007)

Hazards – Failure of Performance

Failure of the sterilization process can lead to incidence of cross contamination, the transmission of potentially infectious organisms from one infected person to another who was not otherwise infected prior to the incident.

To avoid failure, the user must ensure that the materials, instruments and devices to be sterilized are thoroughly cleaned, the manufacturer's instructions for use are followed, the cycle to be used for each type of sterilizer load has been validated, the sterilizer has been maintained in accordance with the sterilizer manufacturer's recommended maintenance schedule and is operating properly, and each sterilizer load is monitored with available and validated biological and chemical sterilization process indicators.

The technology designed into STERIS steam sterilizers including the AMSCO Chimeron Steam Sterilizers provide control safeguards that abort the cycle and give appropriate signals, alerts and warnings when required conditions have not been met or when a malfunction occurs.

Conclusion

The AMSCO Chimeron Medium Steam Sterilizer has been validated to meet the requirements of ANSI/AAMI ST8: 2008, December 4, 2008.

The results of the AMSCO Chimeron Medium Steam Sterilizer validation studies demonstrate that the sterilizer performs as intended.

Based on the information provided in this premarket notification, it can be concluded that the AMSCO Chimeron Medium Steam Sterilizer is substantially equivalent to the predicate device and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert F. Sullivan
Senior Director, FDA Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

DEC 16 2011

Re: K112055
Trade/Device Name: AMSCO Chimeron Medium Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: December 2, 2011
Received: December 5, 2011

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112055

Indications for Use

510(k) Number (if known):

Device Name: AMSCO Chimeron Medium Steam Sterilizer

Indications For Use:

The AMSCO Chimeron Medium Steam Sterilizers (Models 36H, 48H, 60H, 36SL, 48SL, 60SL, 36CH, 48CH, 60CH, 36CSL, 48CSL and 60CSL) are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in the following configuration:

- *Prevacuum* – equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.

The AMSCO Chimeron Medium *Prevacuum* Steam Sterilizers are equipped with the following factory-programmed sterilization cycles and cycle values (Table 4-1):

Table 4-1.
AMSCO Chimeron Medium *Prevacuum* Steam Sterilizer factory-validated sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
Prevac	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. *Refer to Table 4-2 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. *Refer to Table 4-2 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 4-2 for recommended quantities.*
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 4-2 for recommended quantities.*

The following table is a guideline for liquid cycle processing:

Table 4-3
AMSCO Chimeron Medium Steam
Sterilizer Liquid Cycle Guideline

Sterilizer Size	Number of Containers for full load	Number of Containers for validation	Volume of Liquid In One Container	Minimum Recommended Sterilize Time at 250°F (121°C)
26" x 37.5" x 36"	112	3	1000 ml	45 minutes
26" x 37.5" x 48"	154	3	1000 ml	45 minutes
26" x 37.5" x 60"	196	3	1000 ml	45 minutes

*The liquid cycle is for non-patient contact use only.

The AMSCO Chimeron Medium Steam Sterilizer is offered in the following chamber sizes:

- 26" x 37.5" x 36" (Models 36H, 36CH, 36SL, 36CSL)
- 26" x 37.5" x 48" (Models 48H, 48CH, 48SL, 48CSL)
- 26" x 37.5" x 60" (Models 60H, 48CH, 48SL, 48CSL)

Prescription Use _____ AND/OR Over-The-Counter Use __X_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112055